

Opening Statement of the Honorable Tim Murphy
Subcommittee on Oversight and Investigations
Hearing on “Counterfeit Drugs: Fighting Illegal Supply Chains”
February 27, 2014

(As Prepared for Delivery)

The subcommittee meets to examine the growing problem of counterfeit drugs. Another fitting title for our hearing today: “Poison Pills in Your Medicine Cabinet: Counterfeiters Deliver Deadly Drugs.”

Last year Congress took an important first step against this threat by enacting the new track-and-trace law known as the Drug Quality and Security Act of 2013. This new law will secure the legitimate distribution channels, and when implemented will solve the legal supply chain part of the counterfeit drug problem.

However, many Americans purchase medicines through illegal supply chains, such as rogue Internet pharmacies and other black markets. It is that part of the counterfeit drug threat we address today. This hearing focuses on the illegal supply chains of counterfeit drugs, and on efforts to deter and disrupt these illegal supply chains.

The legitimate U.S. drug supply is safe. But counterfeit drugs from illegal sources are a significant and growing global public-health threat, potentially causing treatment failure or death and contributing to increased anti-microbial resistance. The policy of the U.S. government is not to wait for a full-blown crisis before taking appropriate action.

Drug counterfeiters do not just steal intellectual property. They recklessly and intentionally endanger human lives.

They sell counterfeits that do not contain active ingredients and provide no treatment benefit to the patient. Thus, a child suffering from malaria who takes a fake anti-malaria drug might die within 48 hours because the malaria remains untreated.

The counterfeiters sell fakes that may contain incorrect ingredients, improper dosages, hazardous, or poisonous ingredients. For example, an emergency room doctor from Texas in 2011 took a counterfeit weight loss drug he bought from an online pharmacy. The drug was contaminated with a controlled substance and he suffered a stroke.

The counterfeiters sell drugs with risks for harmful side effects or allergic reactions. For example, in 2007 and 2008, dozens of heart-surgery and kidney-dialysis patients in the U.S. suffered unexpected allergic-type reactions and several lost their lives due to intentionally contaminated heparin imported from China that had entered the Chinese heparin supply purporting to be pure heparin.

The counterfeiters do not care about the patients who are hurt. One counterfeiter, Richard Taylor, was notified in May 2011 that two patients who had been on a counterfeit cancer drug he had distributed had started to shake in the middle of being transfused and had to be disconnected from treatment.

However, the penalties for drug-counterfeiting under the Federal Food Drug and Cosmetic Act have not been updated since 1938. As the FDA Commissioner has said, there is a steeper penalty for counterfeiting a designer purse under the Federal Criminal Code than a drug product under current FDA law.

Drug counterfeiting is highly profitable, and the criminals only face the maximum penalties under the FDA law of \$10,000 or three years in prison. In contrast, penalties for trafficking narcotics can have prison sentences up to life and fines in the millions of dollars. There is one estimate that the return on counterfeit drugs may be 10 times greater than that of the sale of illegal narcotics.

Experts tell us the counterfeit drug problem has worsened over the last decade. The reasons for this disturbing trend include: increasing opportunities created by larger, more complex supply chains; more customers reachable through the Internet; more cases where the counterfeiting crimes occur in several countries making enforcement more difficult; and the expansion of counterfeiting from so-called lifestyle drugs into therapeutic medicines used to treat cancer, heart disease, or other illnesses.

The illegal supply chains are numerous and global. Rogue Internet pharmacies are proliferating. There are believed to be about 35,000-50,000 active online sellers, 97 percent of which do not comply with U.S. laws, according to one review of over 10,000 Internet sites. One report estimated that one in six Americans – 36 million people – have bought medicines online without a valid prescription. These illegal pharmacy operations are big business, with the largest ones reportedly making \$1 to 2.5 million dollars of sales a month.

The sheer volume of imported drugs into the U.S. is overwhelming and opportunities have never been greater for foreign unapproved drugs to get into the U.S. Nearly 40 percent of drugs taken by Americans are made overseas and 80 percent of the active ingredients are imported from about 3,800 foreign manufacturers, in more than 150 countries. According to a 2011 FDA report, the number of foreign drug suppliers has doubled in the last seven years. The Government Accountability Office (GAO) has found FDA is only able to inspect foreign drug plants every nine years while FDA inspects domestic drug manufacturers about every two years.

The subcommittee will also examine other illegal supply chains such as medical clinics and doctors who purchase drugs from illegal sources, business-to-business (B2B) networks, and smugglers bringing unapproved or counterfeit drugs from Mexico into the U.S.

I welcome all of today's outstanding witnesses and look forward to their testimony.

###